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Mr. Robert L. Stephenson II, MPH
Director, Division of Workplace Programs
CSAP, 5600 Fishers Lane
Rockwall II, Suite 815
Rockville, MD 20857

VIA FACSIMILE

Dear Mr. Stephenson:

These comments are in response to the proposed revisions to the mandatory guidelines for Federal workplace drug testing programs, published in the *Federal Register* August 21, 2001. We applaud the efforts of the Division of Workplace Programs and the Drug Testing Advisory Board to provide structure and guidelines for what has become a very complex issue in drug testing programs. The comments refer to specific sections of the proposed revisions as published.

2.4 (g)(1)(iii)
Laboratory experience indicates that the prevalence of specimens with pH outside the defined range of 3.1 – 11.0 is extremely low. The value of testing each specimen submitted for pH is questionable with regard to total outcome. The added costs may not justify its inclusion in the standard SVT panel, and should be reserved for situations when additional testing is indicated.

2.4(g)(4)
The description of when a specimen is reported as dilute uses the terminology "when the initial or confirmatory tests have creatinine and specific gravity results". This section should be clarified to indicate that determination of dilute may be based on tests on initial aliquot and only one determination of creatinine and specific gravity are required.

2.4(g)(5)(iv)
The additional definitions of 'invalid' based on incongruent creatinine and specific gravity results are confusing and may lend themselves to errors in interpretation of results by laboratories/MROs. We are not convinced that the available data support the expansion of this category to include the combinations of creatinine and specific gravity utilized in the definition.

2.4(g)(5)(v)
Inclusion of pH parameters in this definition again adds a level of complexity to the interpretation of SVT results that is of questionable value to the overall effectiveness of the program. We recommend that the program continue to utilize the cutoffs of 3 and 11 which are clearly beyond normal physiologic values.

2.4(k)(1)(iii)
This paragraph specifies LOD/LOQ as criteria for reconfirmation of the presence of an adulterant that does not have a specific cutoff. This language is inconsistent with current guidelines that indicate retests for drugs/drug metabolites are performed to assay LOD. Recommend modifying language to use 'LOD'.

2.5(e)(2)
Testing for creatinine in the laboratory is well established and the most common methods are sufficient for use in the context of SVT. Assay calibration at 100 mg/dl is common and provides the dynamic range, precision and accuracy required. Inclusion of a control at the decision points is sufficient to routinely verify the performance of the analysis at those levels. Addition of calibration standards at 5 and/or 20 mg/dl requires revalidation of the assay that is not necessary.

2.5(e)(3)
Quality control at the decision points of 5 and 20 mg/dl is an important measure of routine assay performance at those levels. An additional QC sample in the normal range (>20 mg/dl) should also be included to control performance in the normal range which includes 95% of samples tested. The limits for the QC listed in this section should be revised to reflect the ranges indicated above.

2.5(e)(4)
The above comments regarding assay calibration apply to this paragraph. QC focused on the low decision point for the confirmatory test is appropriate.

2.5 (f)(3)
This paragraph requires 4 QC samples: one at 1.001, one between 1.002 and 1.010, one in the range 1.020 – 1.025 and one in the range 1.015 – 1.020. This is excessive and does not add value to the SVT process. The required QC should include one at each decision point (<1.002, >1.020) and one in the normal range (1.003 – 1.019).

2.5(g)(4)
The number of controls in this section exceeds what is required to ensure the accuracy of the measurement at the indicated levels. In reference to the comments regarding definitions of 'invalid' specimens in the pH ranges 3 – 3.9 and 10 – 10.9, the elimination of these categories eliminates the necessity of pH controls at those levels. There is also an inconsistency between QC requirements for initial pH testing when using colorimetric vs. pH meter as the initial test.

General comments with regard to other adulterants: When identification of an adulterant involves a compound that may occur in a urine sample from normal physiologic processes or via occupational or environmental exposure (e.g. nitrite), it is important to define levels which are consistent with normal exposures vs. levels that are consistent with adulteration. This has been done with nitrites. We would recommend that since significant databases exist for occupational and environmental exposure to chromium, that a similar review should be performed to define normal vs. abnormal levels, regardless of the species.

Thank you for the opportunity to provide input into the rulemaking process.

Sincerely,

Dr. Jennifer A. Collins/po.

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